

**Remarks**

**The Claim Amendments**

Applicant has cancelled claims 4-9, previously withdrawn, and claims 13-14.

Claims 1-3, 11-12 and 15-16, therefore, remain in the application.

Applicant has amended claim 1 to clarify that the first and the second plurality of variable polynucleotides encode a first and a second plurality of variable polypeptides, respectively. Applicant has also amended claim 1 to clarify that the first plurality of variable polynucleotides is located in the first cloning region and the second plurality of variable polynucleotides is located in the second cloning region. Finally, applicant has amended claim 1 to avoid the term "possibly" and to use the better "group consisting of" language. Support for these amendments can be found, e.g., on page 8, lines 26-31; page 140, lines 25-27 and page 147, line 29 to page 148, line 26. None of these amendments narrow the claims. They merely clarify the original claim scope.

Applicant has amended claims 11 and 12 to recite the characteristics of the vectors that characterize the plurality of polynucleotides of claims 1 and 2. The claims previously recited these characteristics by back references to these claims. Accordingly, these amendments do not narrow the scope of the claims and are not new matter.

Applicant has amended claims 3, 15 and 16 to clarify the Fab libraries encoded by the claimed polynucleotides. These amendments are not new matter and do not narrow the scope of the claims.

These amendments are in full accordance with 37 C.F.R. § 1.116. They cancel claims (claims 4-9 and 13-14). They amend rejected claims to place them in better form for appeal. And, as discussed below, the amendments specifically suggested by the Examiner place the claims in condition for allowance. Applicant respectfully requests entry of the amendments after final.

Rejections

35 U.S.C § 102(a) – EP 844306 A1

The Examiner has rejected claims 1-3 and 11-16 under 35 U.S.C. §102(a) as anticipated by EP 844306 A1 (the '306 application). The Examiner states that the '306 application "teaches DNA encoding a genetically diverse population of specific binding pairs in recombinant host cells." More specifically, the Examiner states that the '306 application "teaches a library of  $10^{14}$  possible clones expressing the combination of H and L chains". The Examiner also states that the vector of the '306 application "comprises rbs at the 5' end of the cloning regions, restriction enzyme sites and first and second cloning regions comprising  $V_H$  and  $V_L$  antibody fragments, gIII at the 3' end of the second cloning region (e.g., see figure 27)." The Examiner further states that "the vector has a sequence encoding a C-terminal peptide tag for detection" (see page 46 of the '306 application). Applicant traverses.

Claims 1-3, 11-12 and 15-16, the only claims remaining in the case, recite a plurality of vectors which comprise a first and a second plurality of variable polynucleotides. The claims further recite that the first and second plurality of polynucleotides encode a first and

second plurality of variable polypeptides, respectfully. The '306 application does not disclose any such vector(s).

The '306 application refers to five alleged approaches for making a library of combinations of VH and VL chains. See p.6, lines 12-48. Only the fourth approach refers to a vector or library where "both chains are cloned into the same vector." See p. 6, lines 41-42. Thus, only the fourth approach is even potentially relevant to the claims of the instant application, where two pluralities of variable polynucleotides are cloned into the same vector. The fourth approach of the '306 application does not, however, teach a library of vectors characterized by two pluralities of variable polynucleotides that each encodes a plurality of variable polypeptides. Rather, in the fourth approach of the '306 application, one of the polypeptide chains is kept fixed. See, p. 6, lines 42-44.

Hence, even if, as the Examiner asserts, the fourth approach of the '306 application employs a first and second plurality of polynucleotides, one of those pluralities is degenerate and encodes a single, fixed polypeptide.

As a consequence, in this approach this one fixed polypeptide is matched with a plurality of variable polypeptides. See, example 22. This approach, thus, does not produce a library of  $10^{14}$  possible clones. At best,  $10^7$  clones are produced. The citation on page 6 refers to the possible combinations in the second approach. That is irrelevant here because that approach does not clone the two sets of nucleotides in the same vector. See, page 6, lines 16-26.

The amended claims are not anticipated by the '306 application. Indeed, applicant amended the claims, as suggested by the Examiner's response to his previous arguments, to make clear that both the first and second plurality of polynucleotides and the two sets of polypeptides coded for by them are variable, not fixed. Thus, the claimed libraries and vectors are characterized by a first plurality of variable polynucleotides and a second plurality of variable polynucleotides, each encoding respective plurality of polypeptides. There is no fixed polypeptide. Thus, in principle, a library of  $10^{14}$  possible clones could be produced using applicant's invention.

Accordingly, applicant respectfully requests that the Examiner withdraw her 35 U.S.C. § 102(a) rejection and allow amended claims 1-3, 11-12 and 15-16.

35 U.S.C. § 102(e) – US Patent 5,969,108

The Examiner has rejected claims 1-3, and 11-16 under 35 U.S.C. §102(e) as anticipated by US Patent 5,969,108 (the '108 patent). In substance, this is the same rejection as that under the '306 application. Indeed, the '108 patent has the same specification as the '306 application. Applicant traverses.

For all of the reasons explained above in the context of the '306 application, the '108 patent does not anticipate the amended claims. Accordingly, applicant respectfully requests that the Examiner withdraw her 35 U.S.C. § 102(e) rejection and allow amended claims 1-3, 11-12 and 15-16.

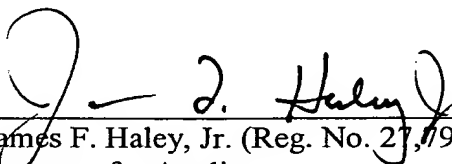
35 U.S.C § 102(e) – US Patent 6,172,197 B1

The Examiner has rejected claims 1-3 and 11-16 under 35 U.S.C. §102(e) as anticipated by US Patent 6,172,197 (the '197 patent). In substance, this is the same rejection as the previous two rejections. Applicant traverses and for the same reasons requests that the Examiner withdraw her 35 U.S.C. § 102(e) rejection and allow claims 1-3, 11-12 and 15-16.

**CONCLUSION**

Applicant requests that the Examiner enter the above amendments, consider the foregoing remarks, and allow the pending claims to issue.

Respectfully submitted,

  
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